JUN 1 6 2000

K000892

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda EEG module, M-EEG and the Datex-Ohmeda EEG headbox , N-EEG and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876
Tel: 978-640-0460
Fax: 978-640-0469

NAME OF CONTACT:

Mr. Joel Kent
FDA Official Correspondent

DATE:

March 17, 2000

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda EEG module, M-EEG and the Datex-Ohmeda EEG headbox , N-EEG and accessories

COMMON NAME:

EEG Measurement Module, EEG Measurement Headbox, and EEG Accessories

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

Electroencephalograph (per 21 CFR 882.1400)
Stimulator,Auditory,Evoked response (per 21 CFR 882.1900)
Electromyograph, diagnostic (per 21 CFR 890.1375)

The following Class I classifications appear applicable:

Electroencephalogram (EEG) signal spectrum analyzer (per 21 CFR 882.1420)

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda EEG Module M-EEG, the Datex-Ohmeda EEG Headbox N-EEG and accessories are subtantially equivalent to two legally marketed devices (predicates). A comparison is made between the Datex-Ohmeda EEG Module combined with Datex-Ohmeda EEG Headbox and predicates the Moberg Medical, Inc Neurotrac II-EP (K960170) and the Datex ABM Anesthesia and Brain Monitor (K821910).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda EEG module, M-EEG is a single-width plug-in parameter module for a modular monitoring system. This module is designed for use in the following Datex-Ohmeda modular monitors; AS/3 Anesthesia Monitor, AS/3 Compact Monitor, CS/3 Compact Monitor and CS/3 Critical Care Monitor. The Datex-Ohmeda EEG module, M-EEG is for controlling the EEG, FEMG and AEP measurements in the N-EEG.

The Datex-Ohmeda EEG headbox, N-EEG is a separate preamplifier and measurement unit for EEG, FEMG and AEP measurements. N-EEG can measure up to 4 real-time EEG waveform channels and an FEMG measurement from one channel. It can also measure AEP from two channels. The N-EEG can only be used with the Datex-Ohmeda EEG module, M-EEG.
The raw EEG signal is displayed from all the monitored channels. The waveform size, color and sweep speed can be adjusted.

Spectral analysis is performed on all of the measured EEG channels. Total power is calculated, and several parameters are calculated based on the power spectrum of the signal. The burst suppression pattern is detected, and suppression ratio is calculated. All the calculated parameters can be selected on the display, and trended.

For auditory evoked potentials, the stimulation intensity and frequency can be set, and the number of averaged responses can be determined. The averaged AEP can be stored and markers can be set manually. Six sets of AEP's can be stored and printed. One of the saved responses can be selected as a reference on screen.

Electrode impedance is measured automatically, when the electrodes are attached, and during monitoring at user-defined intervals.

There are no alarms associated with the measurement, except for a message and an auditory beep for leads off situations. To simplify the patient connections, a series of preconfigured lead sets for different EEG measurements are available. The lead wires are connected together by a plastic piece, which has labels indicating where to attach which lead. The lead wire goes through the plug so that the connectors of the wire are visible from the other side to be plugged into the headbox. The lead set has an identification pin by which the monitor can automatically select the correct montage. There are 8 different lead sets, of which 3 are preconfigured and 5 are empty ones, for the user's own montages. The length of the leads is 0.60 m. The headphones for AEP monitoring are connected to a standard 3.5 mm stereo female plug in the headbox. The headphones supplied by Datex-Ohmeda generate the sound wave in a speaker, from where the pulse is transmitted to the ear through plastic tubes. Standard safety pin EEG leads and commercial headphones can also be used with the device.

Datex-Ohmeda will supply two types of commercially available electrodes: those recommended outside the hairline, and those inside the hairline.

INTENDED USE as required by 807.92(a)(5)

The Datex-Ohmeda EEG module , M-EEG and the Datex-Ohmeda EEG headbox , N-EEG are intended to be used with Datex-Ohmeda modular multiparameter monitors for monitoring neurophysiological status of hospitalized patients.

The Datex-Ohmeda EEG module , M-EEG and the Datex-Ohmeda EEG headbox , N-EEG and accessories are indicated for monitoring of electroencephalograph (EEG), frontal electromyograph (FEMG) and auditory evoked potentials (AEP) of all hospital patients.

The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda EEG Module M-EEG, the Datex-Ohmeda EEG Headbox N-EEG and accessories have been compared to two legally marketed devices (predicates). A comparison is made between the Datex-Ohmeda EEG Module combined with Datex-Ohmeda EEG Headbox and predicates the Moderg Medical, Inc Neurotrac II-EP (K960170) and the Datex ABM Anesthesia and Brain Monitor (K821910).

The comparison to the Neurotrac II-EP discusses general specifications, and the EEG and AEP portion of the two devices.

For the predicate Datex Anesthesia and Brain Monitor predicate, the comparison is made only to the frontal EMG (FEMG) measurement.

The Datex-Ohmeda Module M-EEG is a single-width plug-in parameter module which is used in conjunction with the Datex-Ohmeda EEG Headbox N-EEG to measure four channels of EEG, FEMG amplitude from one channel, to stimulate the brain with auditory stimuli and to measure the auditory evoked potentials (AEP) from two channels. The Datex-Ohmeda EEG Module M-EEG and the Datex-Ohmeda EEG headbox N-EEG and accessories can be used in the following Datex-Ohmeda modular monitors: AS/3 Anesthesia Monitor (AM), AS/3 Compact Monitor (CM), CS/3 Critical Care Monitor (CCM) and CS/3 Compact Monitor (CMC).

The Datex-Ohmeda EEG module M-EEG, the Datex-Ohmeda EEG Headbox N-EEG and accessories and the predicate Neurotrac II-EP both monitor several channels of EEG and auditory evoked potentials. Both of the devices are designed as a bedside continuous EEG/EP monitor to be used in the hospital.

The EEG measurement in the Datex-Ohmeda EEG module, EEG headbox and accessories compared with the predicate Neurotrac II-EP (K960170) have similar specifications overall. The main differences in the EEG measurement in the Datex-Ohmeda EEG module, EEG headbox and accessories compared with the predicate Neurotrac II-EP (K960170) are:

- The product structure: the predicate is a stand-alone device, whereas the new device is a module inserted in a patient monitor

- The number of channels for EEG is greater in the predicate device (8 versus 4) than in the new device, but 4 channels are widely used and considered adequate for EEG monitoring.

- There are more filtering options in the predicate device, however, the filters used in the new device are acceptable for non-diagnostic EEG monitoring since most EEG information is below 30 Hz.

- The predicate device stores 24 hrs of raw EEG internally whereas the new devices store only snapshots based on user input.

- There are differences in the calculated parameters in that the predicate has additional power and frequency spectrum calculations and the new device calculates burst suppression ratio when the predicate does not. The new device also calculates EEG amplitude whereas the predicate displays total power. Either amplitude (more commonly used) or power are acceptable means to display the same data according to guidelines. Since there are no universally accepted calculated EEG parameters these displayed values have no effect on patient safety.

- The impedance measurement is continuous in the predicate device, but intermittent (every 5 minutes minimum) the Datex-Ohmeda device. Both devices have instantaneous leads off detection.

The AEP measurement in the Datex-Ohmeda EEG module, EEG headbox and accessories compared with the predicate Neurotrac II-EP (K960170) have many similar specifications. The main differences in the AEP measurement in the Datex-Ohmeda EEG module, EEG headbox and accessories compared with the predicate Neurotrac II-EP (K960170) are:

- In the predicate there are more options for the measurement in terms of filtering, stimulation intensity and frequency and the number of averaged responses. For monitoring, with the new device, the filtering, stimulation intensity and frequency and number of averaged responses although different are considered acceptable

- The sampling frequency and the frequency response is different. Although the predicate has a higher sampling rate the rate used in the new device is adequate to resolve the AEP signals found below 500Hz

The FEMG measurement principle in the Datex-Ohmeda EEG module, EEG headbox and accessories compared with the predicate Datex Anesthesia and Brain Monitor (K821910) is the same. The main differences in the FEMG measurement in the Datex-Ohmeda EEG module, EEG headbox and accessories compared with the predicate Datex Anesthesia and Brain Monitor (K821910) are:

- There is an adjustable alarm for high EMG in the predicate and no alarm in the new device.

- The frequency response and measurement range is slightly different, but not enough to have a significant effect on the measurement.

It is evident that the main features and indications for use of Datex-Ohmeda EEG Module combined with Datex-Ohmeda EEG Headbox are substantially equivalent to the predicates Moderg Medical, Inc Neurotrac II-EP (K960170) and Datex ABM Anesthesia & Brain Monitor (K8821910).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda EEG module, M-EEG and the Datex-Ohmeda EEG headbox , N-EEG and accessories is in compliance with safety standards and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance to the following mandatory and voluntary standards have been made:

- FDA regulation 21 CFR 898.12
- IEC 60601-1: 1988 +Amdt 1:1991, Amdt 2:1995
- EN 60601-1 1990+Amendments: A1:1993, A2:1995, A13:1996
- CAN/CSA C22.2 No. 601-1-M90 +S1 (1994)+Amdt2:1998
- UL 2601-1: 1997
- IEC 60601-1-2
- IEC 60601-1-4
- ANSI/AAMI ES1 (1993)
- IEC 601-2-26 (1994)

Conclusion:
The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda EEG module, M-EEG and the Datex-Ohmeda EEG headbox , N-EEG and accessories as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2000

Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
Datex-Ohmeda, Inc.
3 Highwood Drive
Tewksbury, Massachusetts 01876

Re: K000892
Trade Name: Datex-Ohmeda EEG module, M-EEG and
the Datex-Ohmeda EEG headbox, N-EEG and accessories
Regulatory Class: II
Product Code: GWQ, GWJ, IKN
Dated: March 17, 2000
Received: March 20, 2000

Dear Mr. Kent:

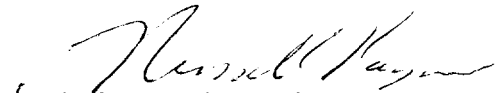
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000892

Device Name: **Datex-Ohmeda EEG module , M-EEG and the Datex-Ohmeda EEG headbox , N-EEG and accessories**

The Datex-Ohmeda EEG module , M-EEG and the Datex-Ohmeda EEG headbox , N-EEG and accessories are indicated for monitoring of electroencephalograph (EEG), frontal electromyograph (FEMG) and auditory evoked potentials (AEP) of all hospital patients.

The device is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000892